
Report of the international conference on manufacturing and testing of pluripotent stem cells.

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Public Summary:

International Alliance for Biological Standardization (IABS) sponsored a public scientific meeting on cell therapy which was generously supported by the California Institute for Regenerative Medicine (CIRM). Sessions included an overview of past cell therapy (CT) conferences sponsored by the International Alliance for Biological Standardization. The sessions highlighted challenges in the field of human pluripotent stem cells (hPSCs) and also addressed specific points on manufacturing, bioanalytics and comparability, tumorigenicity testing, storage, and shipping. Panel discussions complemented the presentations. The conference concluded that a range of new standardization groups is emerging that could help the field, but ways must be found to ensure that these efforts are coordinated. In addition, there are opportunities for regulatory convergence starting with a gap analysis of existing guidelines to determine what might be missing and what issues might be creating divergence. More specific global regulatory guidance, preferably from WHO, would be welcome. IABS and CIRM will explore with stakeholders the development of a practical and innovative road map to support early CT product (CTP) developers.

Scientific Abstract:

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